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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,388	11/25/2003	Pero Dimsoski	5135 US	7966

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
850 LINCOLN CENTRE DRIVE
FOSTER CITY, CA 94404

EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/723,388	DIMSOSKI ET AL.
	Examiner	Art Unit
	Stephanie K. Mummert	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.U.O.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

2. The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.48. Three inventors: Dimsoski, Woo and Webster are listed on the Application Data Sheet submitted November 25, 2003. The signed oath submitted on September 9, 2004 does not include information or a signature for Jeremy Webster. Clarification of the intended inventorship is required.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 1 and page 27). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Interpretation

The term 'mobility modifier' is being given the broadest reasonable interpretation in light of the specification. In the specification, the term is defined that it 'refers to at least one polymer chain that when added to at least one reaction component that affects the mobility of the element to which it is bound'. The examiner reads that

definition broadly to include any type of polymer, including polynucleotides, polypeptides, or synthetic polymers, for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 8-11 and 16-17 rejected under 35 U.S.C. 102(b) as being unpatentable over Caskey (US Patent 5,364,759; November 1994). Caskey teaches a method of DNA typing for the detection of short tandem repeat polymorphisms. Caskey teaches all of the limitations of claims 1-5,8-11 and 16-17, as follows:

5. With regards to claims 1 and 16, Caskey teaches a method for isolating a labeled single-stranded target polynucleotide, forming a PCR reaction mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also column 3, lines 33-51),

b. a first primer specific for the region of interest, wherein the primer has a label

(column 3, lines 52-59) and a mobility modifier (column 10, lines 47-48, where a linker of DNA, which is being interpreted to be a mobility modifier, is attached to one of the primers),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (column 10, lines 54-55 where one primer is biotinylated), thereby forming a reaction mixture, amplifying the region of interest (column 10, lines 43-59), contacting the reaction mixture with a binding moiety specific for the affinity moiety, binding the double stranded amplification product to the binding moiety (column 10, lines 56-57), removing the unbound unincorporated reaction components, and releasing the labeled single-stranded target polynucleotide by denaturation (column 10, lines 63-67). Each step of this method is also detailed in Figure 1.

6. With regards to Claims 2, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the mobility modifier is polynucleotide linker molecule (Figure 1, see also, column 10, lines 47-48, where a linker of DNA is attached to one of the primers).

7. With regards to Claim 3, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the binding moiety is streptavidin (column 10, lines 56-57, see also Figure 2).

8. With regards to Claim 4, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the affinity moiety is biotin (column 10, lines 56-57, see also Figure 2).

9. With regards to Claims 5 and 17, Caskey teaches the limitations of the method of Claim 1 wherein the PCR mixture further comprises a plurality of primer sets (Table 6, where a representative list of the multiple STRs analyzed are listed), wherein the first primer further comprises the label (column 3, lines 52-55) and the mobility modifier (column 10, lines 47-48, where a linker of DNA is attached to one of the primers), and wherein the second primer further comprises the affinity moiety (column 10, lines 54-55 where one primer is biotinylated).

10. With regards to claims 8-11, Caskey teaches the amplification of regions of interest that comprise polymorphic microsatellites (column 3, lines 3-5) and further teaches that these polymorphic microsatellites can further comprise dinucleotide, trinucleotide, and tetranucleotide repeats (column 3, lines 34-51, where a short table describes the possible types of repeats).

11. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tully et al. (Genomics, 1996, 34:107-113). Tully teaches a method of multiplex solid-phase fluorescent mini-sequencing using mini-sequencing primers of differing electrophoretic mobility (p. 107, column 2, lines 4-23). Tully teaches all of the limitations of Claims 18-19, as follows:

12. With regard to Claim 18, Tully teaches a method for isolating a labeled single stranded target polynucleotide and forming a PCR mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also p. 107, column 2, lines 4-7),

b. a first primer specific for the region of interest (Figure 1, see also Table 1),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (Figure 1, see also Table 1, where one of the pair of primers are labeled with biotin), amplifying the region of interest (Figure 1, see also p. 108, column 1, lines 10-21), contacting the reaction mixture with a binding moiety specific for the affinity moiety, binding the double stranded amplification product to the binding moiety (Figure 1, see also p. 108, column 2, lines 4-17 where the PCR products are bound to streptavidin coated magnetic beads), removing the unbound unincorporated reaction components (p. 108, column 2, lines 4-17, where the bound PCR products were washed six times as described), and eluting and removing the unlabeled single-stranded target polynucleotide (p. 108, column 2, lines 4-17, where the PCR product is denatured and washed with 0.15M NaOH, see also p. 109, column 2, lines 15-17) and providing,

a. a polymerase (Figure 1, see also, p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15),

b. a primer complementary to the bound second strand, wherein the primer further comprises a mobility modifier (Table 2, see also p. 110, column 1, lines 22-31, where the mobility modifiers are extended poly(A) tails), and,

c. at least one dye-labeled nucleotide (Figure 1, see also, p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15), performing an extension reaction to form a

labeled single stranded target polynucleotide, and releasing the labeled single stranded target polynucleotide (Figure 1, see also p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15).

13. With regards to Claim 19, wherein the labeled single stranded polynucleotide is analyzed by mobility-dependent analysis technique (Figure 1, see also p. 109, column 1, lines 16-26).

Therefore, Caskey and Tully meet all of the limitations of Claims 1-5, 8-11, and 16-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey (US Patent 5,364,759; November 1994) in view of Butler et al. (From IDS, Citation 18; 2003, J. Forensic Sci, volume 48(5), pages 1-11). Caskey teaches a method of DNA typing for the detection of short tandem repeat polymorphisms. Caskey teaches all of the limitations of claims 1-5, 8-11 and 16-17, as follows:

15. With regards to claims 1 and 16, Caskey teaches a method for isolating a labeled single-stranded target polynucleotide, forming a PCR reaction mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also column 3, lines 33-51),

b. a first primer specific for the region of interest, wherein the primer has a label (column 3, lines 52-59) and a mobility modifier (column 10, lines 47-48, where a linker of DNA is attached to one of the primers),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (column 10, lines 54-55 where one primer is biotinylated), thereby forming a reaction mixture, amplifying the region of interest (column 10, lines 43-59), contacting the reaction mixture with a binding moiety specific for the affinity moiety, binding the double stranded amplification product to the binding moiety (column 10, lines 56-57), removing the unbound unincorporated reaction components, and releasing the labeled single-stranded target polynucleotide by denaturation (column 10, lines 63-67). Each step of this method is also detailed in Figure 1.

16. With regards to Claims 2, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the mobility modifier is polynucleotide linker molecule (Figure 1, see also, column 10, lines 47-48, where a linker of DNA is attached to one of the primers).

17. With regards to Claim 3, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the binding moiety is streptavidin (column 10, lines 56-57, see also Figure 2).

18. With regards to Claim 4, Caskey teaches the limitations of the method of Claim 1 (as described above) wherein the affinity moiety is biotin (column 10, lines 56-57, see also Figure 2).

19. With regards to Claims 5 and 17, Caskey teaches the limitations of the method of Claim 1 wherein the PCR mixture further comprises a plurality of primer sets (Table 6, where a representative list of the multiple STRs analyzed are listed), wherein the first primer further comprises the label (column 3, lines 52-55) and the mobility modifier (column 10, lines 47-48, where a linker of DNA is attached to one of the primers), and wherein the second primer further comprises the affinity moiety (column 10, lines 54-55 where one primer is biotinylated).

20. With regards to claims 8-11, Caskey teaches the amplification of regions of interest that comprise polymorphic microsatellites (column 3, lines 3-5) and further teaches that these polymorphic microsatellites can further comprise dinucleotide, trinucleotide, and tetranucleotide repeats (column 3, lines 34-51, where a short table describes the possible types of repeats).

Caskey is silent with regards to the limitations of Claims 6 and 7. Butler teaches development of reduced size STR amplicons as tools for the analysis of degraded DNA obtained from forensic samples. Butler teaches that DNA that is exposed to the elements can lead to degradation 'due to bacterial, biochemical or oxidative processes.' (p. 1, column 1, lines 5-8)

21. With regards to Claim 6, Butler teaches the polynucleotide region of interest is derived from a sample that further comprises degraded DNA (Abstract, lines 3-6, see also, p. 9, column 1, lines 19-28 and Figure 6, where aged bloodstains were studied). With regards to Claim 7, Butler teaches the degraded DNA is reduced in size to between about 60 and 240 nucleotides (Table 1, where the markers are designed to

prevent 'drop out' of alleles due to degradation and the resulting product sizes are within the specified range).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Butler to the teachings of Caskey. The addition of linker arms to the PCR primers allows the practitioner in the field of STR analysis to have greater control over PCR product size(s) and would lends itself to greater flexibility in multiplex analysis of STR alleles. The teachings of Butler allow for more sensitive and robust amplification of DNA that has been obtained from forensic samples and degraded due to age or to exposure to the elements.

One of ordinary skill in the art of analysis of STR analysis and forensic science would recognize the benefit of increased sensitivity, increased ability to multiplex samples, and the ability to amplify DNA that is obtained in a sub-obtimal condition. Successful amplification of degraded or fragmented DNA allows forensic scientists to analyze samples that would have potentially failed attempts to amplify the samples using standard techniques at the time the invention was made.

22. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey in view of Cotticone et al. (US Patent 6,841,349). Caskey teaches all of the limitations of Claims 1 as detailed above. Caskey is silent with regards to the limitations of claims 13-15. Cotticone teaches methods for the reduction of stutter in the amplification of microsatellite repeats.

23. With regards to Claims 13-15, wherein the PCR mixture further comprises sorbitol (claim 13), betaine (claim 14) or sorbitol and betaine (claim 15) together, Coticone teaches the addition of sorbitol (column 1, lines 8-11, see also column 2, lines 20-23), betaine (column 1, lines 8-11, see also column 2, lines 20-23), or sorbitol and betaine in combination (column 1, lines 8-11, see also column 2, lines 20-23) to reduce stutter in the amplification of microsatellite repeat alleles (column 1, lines 7-9).

Cotticone is silent with regards to the primer modifications associated with the method steps of Claim 1. Caskey teaches the amplification of short-tandem repeat polymorphisms using multi-step PCR amplification using unique linker arms and solid-phase DNA sequencing technology. Caskey teaches that this technique has increased sensitivity over conventional techniques and a significant reduction in the time required to obtain results.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Caskey to the teachings of Cotticone. The addition of linker arms to the PCR primers allows the practitioner in the field of STR analysis to have greater control over PCR product size(s) and would lends itself to greater flexibility in multiplex analysis of STR alleles. The teachings of Cotticone add a useful improvement to the method of Caskey, through the reduction of stutter that is a common challenge in the analysis of microsatellite alleles and short-tandem repeat polymorphisms.

One of ordinary skill in the art of analysis of STR analysis and forensic science would recognize the benefit of increased sensitivity, increased ability to multiplex samples, reduction in stutter and a decrease in the time spent to obtain results.

24. Claims 1, 5 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Soper (US Patent 5,846,727) in view of O'Neill (US Patent 6,514,699; February 2003). Soper teaches multiplex solid-phase automated fluorescent sequencing of DNA (column 5, lines 4-5. Soper teaches all of the limitations of Claim 12, as follows:

25. Claim 1 recites a method for isolating a labeled single stranded target polynucleotide via PCR mixture with a target sequence, a first primer and a second primer with an attached affinity moiety (column 5, lines 1-8, where the affinity moiety is biotin). The region of interest is amplified (column 5, lines 8-9, where there is a PCR product), contacted with a binding moiety (column 5, lines 8-10, see also, column 5, lines 23-29, where the capillary tubes are treated with avidin), unincorporated reaction components are removed (column 5, lines 29-30, see also column 8, lines 52-55) and the labeled single-stranded target is released by denaturation (column 5, lines 29-30, see also column 8, lines 41-45). Claim 5 recites the method of Claim 1 wherein the PCR mixture further comprises a plurality of primer sets (column 6, lines 47-49, where the template may be amplified by multiplex PCR), with the plurality of primers with first primer and a second primer with an affinity moiety (column 6, lines 55-56). Claim 12 recites the method of claim 5, wherein at least one of the single stranded target

polynucleotides results from amplification with a primer pair lacking a mobility modifier (see entire document, there is no mention of the use of mobility modifiers).

Soper differs from the limitations of Claim 1, 5 and 12 as it pertains to the issue of the fluorescent label. Soper does not have the fluorescent label attached to the primer and instead uses fluorescent dye-labeled ddNTPs (column 5, lines 41-43, see also, column 8, lines 27-28).

O'Neill teaches a method for simultaneously generating a plurality of polynucleotide sequencing ladders (abstract, lines 1-3) through an amplification method that includes immobilization of the sequencing ladders on a solid-phase (abstract, lines 7-11). O'Neill further teaches two embodiments of the technique, one referred to as "labeled terminator sequencing," where the sequence information may be obtained by using four chain terminators, where each chain terminator (ddNTP) is labeled with a distinctive fluorescent label (column 11, lines 11-15). O'Neill also teaches another embodiment referred to as "labeled primer sequencing" where the primers are labeled and four distinctive primers are used in four separate reaction vessels to obtain the sequence (column 11, lines 16-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of O'Neill, with regards to the optional techniques that can be applied to incorporate fluorescent or radioactive labels in amplification products, to the teachings of Soper. The techniques detailed above, which apply PCR amplification in the presence of fluorescently labeled dideoxy nucleotides, or use PCR primers with fluorescent end-label, when applied to the technique of Claim 12

will arrive at the same end product - a fluorescently labeled, single-stranded DNA attached to a solid-support via a biotin-avidin interaction.

26. Claims 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Tully et al. (Genomics, 1996, 34:107-113) in view of Yeung (US Patent 5,582,705; December 1996). Tully teaches a method of multiplex solid-phase fluorescent mini-sequencing using mini-sequencing primers of differing electrophoretic mobility (p. 107, column 2, lines 4-23). Tully teaches all of the limitations of Claims 18-19, as follows:

27. With regard to Claim 18, Tully teaches a method for isolating a labeled single stranded target polynucleotide and forming a PCR mixture comprising the following components and steps:

a. polynucleotide region of interest (Figure 1, see also p. 107, column 2, lines 4-7),

b. a first primer specific for the region of interest (Figure 1, see also Table 1),

c. a second primer specific for the region of interest, wherein the second primer comprises an affinity moiety (Figure 1, see also Table 1, where one of the pair of primers are labeled with biotin), amplifying the region of interest (Figure 1, see also p. 108, column 1, lines 10-21), contacting the reaction mixture with a binding moiety specific for the affinity moiety, binding the double stranded amplification product to the binding moiety (Figure 1, see also p. 108, column 2, lines 4-17 where the PCR products are bound to streptavidin coated magnetic beads), removing the unbound unincorporated reaction components (p. 108, column 2, lines 4-17, where the bound

PCR products were washed six times as described), and eluting and removing the unlabeled single-stranded target polynucleotide (p. 108, column 2, lines 4-17, where the PCR product is denatured and washed with 0.15M NaOH, see also p. 109, column 2, lines 15-17) and providing,

a. a polymerase (Figure 1, see also, p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15),

b. a primer complementary to the bound second strand, wherein the primer further comprises a mobility modifier (Table 2, see also p. 110, column 1, lines 22-31, where the mobility modifiers are extended poly(A) tails), and,

c. at least one dye-labeled nucleotide (Figure 1, see also, p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15), performing an extension reaction to form a labeled single stranded target polynucleotide, and releasing the labeled single stranded target polynucleotide (Figure 1, see also p. 108, column 2, lines 18-25 and p. 109, column 1, lines 1-15).

29. With regards to Claim 19, wherein the labeled single stranded polynucleotide is analyzed by mobility-dependent analysis technique (Figure 1, see also p. 109, column 1, lines 16-26, where the mobility analysis technique is electrophoresis through a slab polyacrylamide gel).

Tully is silent with regards to the limitation of Claim 20. Yeung teaches the use of capillary electrophoresis in the resolution of DNA sequencing reactions. Yeung teaches that the use of capillary electrophoresis has "greatly improved DNA sequencing rates compared to conventional slab gel electrophoresis." Yeung further teaches an

improvement to conventional capillary electrophoresis through multiplex analysis and other improvements as detailed in the patent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Yeung to the teachings of Tully. The analysis of PCR amplicons using capillary gel electrophoresis instead of slab gel electrophoresis presents the clear benefit of higher resolution, less time spent casting the gel and often a much higher number of samples can be analyzed simultaneously using capillary electrophoresis than can be accomplished using a conventional slab gel.

One of ordinary skill in the art of DNA analysis would recognize the benefit of capillary electrophoresis over more conventional electrophoresis techniques.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0872. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephanie K. Mummert
Patent Examiner

CYNTHIA WILDER
PATENT EXAMINER
5/16/2005